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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,327	09/26/2003	Lance M. Middleton	SPINE 3.0-2144 DIV II	8423

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,327

Applicant(s)

MIDDLETON, LANCE M.

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Respond to Arguments

Applicant's response filed July 26, 2004 has been fully reviewed. The Examiners responses to applicant's arguments have been incorporated in the grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 1 and 17, "each of said longitudinal ends having an outer curvature corresponding to the inward curvature of vertebral end plates of the upper and lower vertebrae" is not supported in the specification and is new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 16, claim 14 from which it depends claims "support surface joined to and extending across said slotted circumferential wall" interpreted as being the end caps that are not monolithically formed.

Regarding new claim 21, "*slit therein extending therethrough continuously from a position adjacent the lower vertebrae and being dimensioned*" is ambiguous. Where does the slit extend continuously to? It is noted that applicant states claim 21 is claim 12 rewritten in independent form however leaves out the language describing the slit extending "*to a position adjacent the lower vertebrae*".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-11, 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Siebels (5,306,310).

Siebels teaches an intervertebral prosthesis which comprises a disc member dimension for insertion within an intervertebral space between adjacent vertebrae having a substantially solid exterior wall having opposed longitudinal ends for positioning adjacent respective upper and lower vertebrae; said wall defining a helical slit extending completely through the wall (interpretation of claim language in claim 1) between elements 13 and 14 or between themselves; the slit is continuous from a position adjacent the upper vertebrae to a position adjacent the lower vertebrae and being dimension to permit the exterior wall to elastically deform along the entire slit when subjected to a load, such as a tensile load or a from twisting.

Regarding claim 1, the claim uses the transitory phrase "comprises" which can include additional elements. The prosthesis is interpreted as only elements 13 and end plates 18; element 14 which fills the slit in a portion thereof has not been included in the interpretation.

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Regarding the new limitation, *"each longitudinal ends having an outer curvature corresponding to the inward curvature of the vertebral end plates of the upper and lower vertebra"*, giving the language the broadest interpretation, end plates 18 are generally circular and inherently have an "outer curvature" and "correspond" to the inward curvature of the vertebra 11 and 12 shown in figure 1. Note applicant's claim 18 which states that an arcuate perimeter defines an outer curvature.

Regarding claim 13 requiring a monolithically formed, the prosthesis is interpreted as only element 13.

See cap 18.

Regarding claims 13 and 16, the disc member is interpreted as being just element 13 or 14.

Claims 1-10 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Beer et al (5,458,642).

Beer et al teaches an intervertebral prosthesis which comprises a disc member (such as 13i only) dimension for insertion within an intervertebral space between adjacent vertebrae having a substantially solid exterior wall having opposed longitudinal ends for positioning adjacent respective upper and lower vertebrae; said wall defining a helical slit extending completely through the wall (interpretation of claim language in claim 1); the slit is continuous from a position adjacent the upper vertebrae to a position adjacent the lower vertebrae and being dimension to permit the exterior wall to

elastically deform along the entire slit when subjected to a load, such as a tensile load or a from twisting.

See cap 11a, 11b.

Regarding the new limitation, "*each longitudinal ends having an outer curvature corresponding to the inward curvature of the vertebral end plates of the upper and lower vertebra*", giving the language the broadest interpretation, ends 11a and 11b have and perimeter which has a curvature as shown in figure 2. The "outer curvature" is fully capable of corresponding to an inward curvature of a vertebra. Note applicant's claim 18 which states that an arcuate perimeter defines an outer curvature.

Applicant's uses the transitory phrase "comprises" allows the prosthesis to include additional elements such as the elastomeric covering 14. The prosthesis is interpreted as only elements 13 and end plates 18; element 14 which fills the slit in a portion thereof has not been included in the interpretation.

Regarding claim 17, it is noted that Figure 2 of Beer et al shows a generally kidney shaped prosthetic disc member wherein the spring walls are substantially solid and have a deformable helical slit therein.

Allowable Subject Matter

Claim 21 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'BSN', with a large, looping flourish extending from the end.

BRUCE SNOW
PRIMARY EXAMINER